

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

Status of the Claims

Claims 1, 5, 16, 17, and 35 are now pending in this application. Claims 1, 16, and 17 are currently being amended. Support for each amendment is believed obvious from the record and is found within in the specification.

Objection to Claims 16 and 17

The Examiner objects to claims 16 and 17 under 37 C.F.R. 1.75(c) as improper for failing to further limit the subject matter of the previous claim. In their present form, claims 16 and 17 avoid this rejection. Accordingly, Applicant respectfully requests withdrawal of this rejection.

Rejection of Claims 1, 16, and 17 under 35 U.S.C. § 112, first paragraph

Claims 1, 16, and 17 remain rejected under 35 U.S.C. § 112, first paragraph, as allegedly indefinite. Specifically, the Examiner asserts that “the limitation ‘a signal sequence’” is indefinite. Office Action at page 3. Applicants respectfully traverse this rejection.

The second paragraph of section 112 requires only that the claims reasonably apprise those skilled in the art of the scope of the claimed invention. *See e.g. Miles Lab, Inc. v. Shandon, Inc.*, 27 U.S.P.Q.2d 1123 (Fed. Cir. 1993), *cert. denied*, 510 U.S. 1100 (1994), *see*

generally M.P.E.P. § 2173.02. Furthermore, it is the Examiner who has the initial burden of demonstrating that one of skill in the art would not appreciate the metes and bounds of the claimed subject matter. M.P.E.P. § 706.03.

Claims 1, 16 and 17, when read in light of the knowledge of one of ordinary skill in the art, are definite. “Signal sequence” is an art-recognized term defined as:

Short sequences that direct newly synthesized secretory or membrane proteins to and through membranes of the endoplasmic reticulum, or from the cytoplasm to the periplasm across the inner membrane of bacteria, or from the matrix of mitochondria into the inner space, or from the stroma of chloroplasts into the thylakoid.

THE ENCYCLOPEDIA OF MOLECULAR BIOLOGY (1994) Kendrew and Lawrence, *eds.*, Blackwell Science Ltd., Osney Means, Oxford, p.1019 (copy enclosed) (parentheticals omitted).

Numerous signal sequences are known in the art and the physical features and functional characteristics are well-understood. For example, signal sequences are typically located at the N-terminus and are cleaved by signal peptidases after movement across the membrane. *Id.* It also is commonly known that signal sequences possess common structural features – a hydrophobic core, comprising at least eight uncharged residues flanked by a polar basic region on the N-terminal side and a hydrophobic region of about six residues ending with a small uncharged residue. This uncharged residue is the site of peptidase cleavage. *Id.* Accordingly, one of skill in the art would readily understand the scope of the claimed subject matter.

The Examiner inquires about the exclusion of a signal peptide from claim 1 and the inclusion in claim 16. The current form of the claims makes this inquiry moot.

Applicants respectfully request withdrawal of the rejection of claims 1, 16 and 17.

Rejection of Claim 1 under 35 U.S.C. § 112, first paragraph

Claim 1 is newly rejected under 35 U.S.C. § 112, first paragraph as allegedly lacking enablement. Specifically, the Examiner asserts that “[t]he specification does not teach SEQ ID NO:2 lacking the first 13 amino acids has gankyrin biological activity.” Office Action at

page 4. The Examiner cites to Wang *et al.* (J. Biol. Chem. 275:507, 2000), Bowie *et al.* Science 247:1306, 1990, Burgess *et al.* (J. Cell Biol. 111:2129, 1990) and Lazar *et al.* (Mol. and Cell Biol. 8:1247, 1988) as purportedly demonstrating that “even a single amino acid substitution or “conservative” amino acid substitution in a protein will often dramatically affect the biological activity and characteristics of a protein.” From this the Examiner concludes, “Considering the state of the art and the limited teachings of the specification, it is concluded that undue experimentation would be required to practice the invention.” Applicant respectfully request withdrawal of this rejection because it is improper.

The evidence and explanation of record does not establish that claim 1 is not enabled. The Manual of Patent Examining Procedure, TRAINING MATERIALS FOR EXAMINING PATENT APPLICATIONS WITH RESPECT TO 35 U.S.C. SECTION 112, FIRST PARAGRAPH – ENABLEMENT CHEMICAL/BIOTECHNICAL APPLICATIONS states:

The Office must accept as being true the statements supporting enablement unless there is an objective reason, usually supported with documentary evidence, to question them, *i.e.*, the burden is on the Office to demonstrate that there is an objective reason, usually supported by documentary evidence, to question the statement.

Example D. Accordingly, the Examiner must provide an objective reason that the claimed polypeptide, namely a polypeptide consisting of an amino acid sequence from Ala at position 14 to Gly at position 226 of SEQ ID NO: 2, does not have a biological activity of gankyrin. Furthermore, such an assertion should be supported by documentary evidence.

The invention of claim 1 provides a “polypeptide consisting of an amino acid sequence from Ala at position 14 to Gly at position 226 of SEQ ID NO: 2 and having biological activity of gankyrin.” Indeed, the Applicant has discovered that an amino acid sequence from Ala at position 14 to Gly at position 226 of SEQ ID NO: 2 has a biological activity of gankyrin. As acknowledged by the Examiner, the specification discloses several biological activities of gankyrin, enhancement of colony formation, tumorigenic properties and suppression of apoptosis induction. *See* Example 4. The specification also discloses methods of assaying biological activities of gankyrin. *Id.*

The Examiner provides no objective reason and certainly no documentary evidence to support her assertion that claim 1 is not enabled. Accordingly, Applicant respectfully requests withdrawal of this rejection.

Rejection of Claims 5 and 35 under 35 U.S.C. § 102

Claims 5 and 35 remain rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Kato *et al.* The Examiner asserts:

Since the protein of art is 100 % identical to instant SEQ ID NO:2 and the specification at Example 4 (pages 55-58) discloses that the various biological activities of gankyrin listed in instant claim 5 is the characteristics of the SEQ ID NO:2, which is encoded by the 678-bp cDNA isolated in Example 1 (pages 45-48), the claims are anticipated by Kato *et al.*

Office Action at page 6.

The evidence and explanation of record does not establish that Kato *et al.* anticipates the instant claims. Kato *et al.* is cited as disclosing the polypeptide of SEQ ID NO: 2. Claim 5 recites a “purified polypeptide that is encoded by a DNA capable of hybridizing under stringent conditions to a DNA having the nucleotide sequence as set forth in SEQ ID NO:1 and that has a biological property of gankyrin selected from the group consisting of an enhancement in the ability of colony formation, a tumorigenic property and a suppression of apoptosis induction, wherein said stringent conditions are defined as washing said hybridized DNA at 50 oC, with 2xSSC and 0.1% SDS”. Claim 35 recites a “purified polypeptide that is encoded by a DNA capable of hybridizing under stringent conditions to a DNA having the nucleotide sequence as set forth in SEQ ID NO: 1 and that has the biological properties of gankyrin, wherein said stringent conditions are defined as washing said hybridized DNA at 65oC, with 0.1xSSC and 0.1% SDS.”

According to the court in *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995), “knowledge of a protein does not give one a conception of a particular DNA encoding it.” It is well-known that each amino acid is encoded by a three nucleotide codon. See THE ENCYCLOPEDIA OF MOLECULAR BIOLOGY, *supra*, p.215 (copy enclosed). This degeneracy of the genetic code

results in each amino acid being encoded by more than one different codon. *Id.* Nucleic acid hybridization exploits the ability of complementary nucleic acid sequences to hydrogen bond to each other. *Id.* at pp. 503-504 (copy enclosed. The ability of one nucleotide to hybridize to another is a function of the nucleic acid sequence of a given nucleotide. *Id.* The degeneracy of the genetic code can result in a number of nucleotides, each of which can encode the same polypeptide, but lack sufficient similarity to allow for hybridization. Therefore, the evidence and explanation of record does not establish that Kato *et al.* discloses a purified polypeptide that is encoded by a DNA capable of hybridizing under stringent conditions to a DNA having the nucleotide sequence as set forth in SEQ ID NO:1 and that has a biological property of gankyrin selected from the group consisting of an enhancement in the ability of colony formation, a tumorigenic property and a suppression of apoptosis induction, wherein said stringent conditions are defined as washing said hybridized DNA at 50 °C, with 2xSSC and 0.1% SDS as recited in claim 5.

The evidence and explanation of record also does not establish that Kato *et al.* discloses a purified polypeptide that is encoded by a DNA capable of hybridizing under stringent conditions to a DNA having the nucleotide sequence as set forth in SEQ ID NO: 1 and that has the biological properties of gankyrin, wherein said stringent conditions are defined as washing said hybridized DNA at 65°C, with 0.1xSSC and 0.1% SDS as recited in claim 35.

Accordingly, Applicant respectfully requests withdrawal of this rejection.

Rejection of Claims 16 and 17 under 35 U.S.C. § 103

Claims 16 and 17 remain rejected under 35 U.S.C. § 103(a) as allegedly obvious over Kato *et al.* in view of Zhang *et al.* and Jamasa *et al.* Specifically, the Examiner asserts that claims 16 and 17 read on the protein taught by Kato *et al.* In their current form, amended claims 16 and 17 avoid this rejection.

Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection.

Conclusion

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,


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Enclosure: THE ENCYCLOPEDIA OF MOLECULAR BIOLOGY (1994) Kendrew and Lawrence, eds., Blackwell Science Ltd., Osney Means, Oxford, pp.215, 503-506, and 1019 (copy enclosed)